JCM Validation Report Form

A. Summary of validation

A.1. General Information

Title of the project	Energy Saving by Introducing High Efficiency Autoclave to Infusion Manufacturing Factory 2
Reference number	ID034
Third-party entity (TPE)	TPE-ID-010 KBS Certification Services Ltd
Project participant contracting the TPE	PT. Otsuka Indonesia,Otsuka Pharmaceutical Factory, Inc.
Date of completion of this report	19/03/2024

A.2 Conclusion of validation

Overall validation opinion	☒ Positive ☐ Negative

A.3. Overview of final validation conclusion

Only when all of the checkboxes are checked, overall validation opinion is positive.

Item	Validation requirements	No CAR or CL remaining
Project design document form	The TPE determines whether the PDD was completed using the latest version of the PDD forms appropriate to the type of project and drafted in line with the Guidelines for Developing the Joint Crediting Mechanism (JCM) Project Design Document, Monitoring Plan and Monitoring Report.	☒
Project description	The description of the proposed JCM project in the PDD is accurate, complete, and provides comprehension of the proposed JCM project.	☒
Application of approved JCM methodology (ies)	The project is eligible for applying applied methodology and that the applied version is valid at the time of submission of the proposed JCM project for validation.	☒
Emission sources and calculation of emission reductions	All relevant GHG emission sources covered in the methodology are addressed for the purpose of calculating project emissions and reference emissions for the proposed JCM project.	☒
	The values for project specific parameters to be fixed *ex ante* listed in the Monitoring Plan Sheet are appropriate, if applicable.	☒
Environmental impact assessment	The project participants conducted an environmental impact assessment, if required by the Republic of Indonesia, in line with Indonesia's procedures.	☒
Local	The project participants have completed a local stakeholder	☒

Item	Validation requirements	No CAR or CL remaining
stakeholder consultation	consultation process and that due steps were taken to engage stakeholders and solicit comments for the proposed project unless a local stakeholder consultation has been conducted under an environmental impact assessment.	
Monitoring	The description of the Monitoring Plan (Monitoring Plan Sheet and Monitoring Structure Sheet) is based on the approved methodology and/or Guidelines for Developing the Joint Crediting Mechanism (JCM) Project Design Document, Monitoring Plan, and Monitoring Report. The monitoring points for measurement are appropriate, as well as whether the types of equipment to be installed are appropriate if necessary.	☒
Public inputs	All inputs on the PDD of the proposed JCM project submitted in line with the Project Cycle Procedure are taken into due account by the project participants.	☒
Modalities of communications	The corporate identity of all project participants and a focal point, as well as the personal identities, including specimen signatures and employment status, of their authorized signatories are included in the MoC.	☒
	The MoC has been correctly completed and duly authorized.	☒
Avoidance of double registration	The proposed JCM project is not registered under other international climate mitigation mechanisms.	☒
Start of operation	The start of the operating date of the proposed JCM project does not predate January 1, 2013.	☒

Authorised signatory:	Mr. ☒ Ms. ☐
Last name: Goyal	First name: Kaushal
Title: Managing Director, KBS Certification Services Ltd	
Specimen signature: [redacted]	Date: 19/03/2024

B. Validation team and other experts

	Name	Company	Function*	Scheme competence*	Technical competence*	On-site visit
Mr. ☒ Ms. ☐	Sanjay Kumar K	KBS Certification Services Ltd	Team Leader and Technical Expert	☒	Authorised	☐
Mr. ☒ Ms. ☐	Kusheru Wibowo	External Individual	Local Expert	☒	Authorised	☒
Mr. ☒ Ms. ☐	Ranganathan Seshan	KBS Certification Services Ltd	Technical Reviewer and Technical Expert	☒	Authorised	☐
Mr. ☐ Ms. ☒	Margaret Francis	KBS Certification Services Ltd	Manager Technical & Cert.	☒	Authorised	☐

Please specify the following for each item.

* *Function: Indicate the role of the personnel in the validation activity such as team leader, team member, technical expert, or internal reviewer.*

* *Scheme competence: Check the boxes if the personnel have sufficient knowledge on the JCM.*

* *Technical competence: Indicate if the personnel have sufficient technical competence related to the project under validation.*

C. Means of validation, findings, and conclusion based on reporting requirements

C.1. Project design document form

<Means of validation>

A series of the JCM approved forms, including Project Design Document (hereinafter referred to as "PDD") form, was checked and confirmed as complete against the JCM Guidelines for developing Project Design Document and Monitoring Report (hereinafter referred to as "JCM Guidelines"): JCM_ID_GL_PDD_MR_ver02.1. A valid form of the PDD of JCM_ID_F_PDD_ver01.1 is used for the PDD version 01.0, dated 19/12/2023 (as the first edition) and for the PDD version 02.0, dated 07/03/2024 (as the second edition). The validation was conducted on the first edition, and the result was reflected on the second edition of PDD appropriately.

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

No CARs/CLs or FARs were raised against the requirement of the template

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements. KBS confirms that the PDD is completed using the valid form of the JCM PDD form and drafted in accordance with the JCM Guidelines for developing PDD and MR.

C.2. Project description

<Means of validation>

The proposed JCM project aims to reduce emissions of greenhouse gas (GHG) by introducing a new type of high efficiency autoclave and a waste hot water recovery system in the Infusion Manufacturing Factory of PT. Otsuka Indonesia. The autoclave is used in the sterilization of infusion solutions. One end of the autoclave is connected to the steam source (the boiler) through the heat exchanger, where steam is supplied at more than 0.49MPa. The circulation water of the autoclave is fed into the heat exchanger to be heated from 30℃ to 121℃ to produce hot water, and then the hot water is circulated back to the autoclave to sterilize the infusion solutions. The values and the accompanying calculations were available in this file: "List of Parameters for MPS spreadsheet.xlsx".

For existing autoclaves, hot water is disposed after circulation and not recovered for reuse, and for each sterilization cycle the water is heated from normal temperature (30℃), resulting in significant fuel (CNG) consumption of the boiler. In contrast, in this project, the hot water drained from the autoclave is recovered by the waste hot water recovery system and stored in the hot water tank. It is then reheated by the steam source from 110℃ to 121℃ to be circulated in the next sterilization process. By reusing hot water in the next sterilization process, the temperature of the water to be raised is reduced.

Therefore, installation of waste hot water recovery system to an infusion manufacturing process (IMP) line reduces the amount of steam supplied by a boiler for heating water. It leads to reduction of fuel (CNG) consumed by the boiler for generating steam, which consequently leads to GHG emission reductions.

The high efficiency autoclave and waste hot water recovery system are manufactured by Hisaka Works, Ltd. CL01 was raised with reference to the description which was subsequently closed

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

CL01 was raised with respect to lack of detail in project description, the fuel used in reference situation and the date of installation of waste hot recovery system in newly installed IMP line. The details of the address was also not mentioned. Based on the satisfactory responses the same was closed.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.
Based on the responses KBS closed the findings after finding the responses reasonable and acceptable

C.3. Application of approved methodology(ies)

<Means of validation>

The project applied the approved methodology of JCM_ID_AM028_ver01.0, "Energy saving by introducing waste hot water recovery system to autoclave in infusion manufacturing process line". The methodology is approved by the electronic decision of Joint Committee on 17/02/2021 and valid as of the time of the validation. KBS assessed whether the selected methodology was applicable to the proposed JCM project. The proposed JCM project applicability was checked against a lone eligibility criteria stipulated in the Approved Methodology. The steps taken to validate each eligibility criterion and the conclusion about its applicability to the proposed JCM project are summarized as below:

Criterion 01: Waste hot water recovery system is newly installed to an autoclave(s) in an infusion manufacturing process line (IMP line).

Justification in PDD: A waste hot water recovery system is newly installed to an IMP line on 9 February 2022. The high efficiency autoclave and a waste hot water recovery system are manufactured by Hisaka Works, Ltd.

Assessment and conclusion: It was assessed from the documentation submitted viz., technical specification and drawings from the manufacturer that the projct is newly installed on 09/02/2022 The specifications was accepted on this date.

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

CL 01 was raised and closed based on the issuance date of document No.8/9 provided on 20 Feb 2024 (delivery specifications and drawings), the installation date "9 Feb 2022" is mentioned in the document. Based upon the cross checking of the evidences, CL01 was clsoed.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

Based on the documentary evidence submitted it is accepted that the project satisfies all the condition of the methodology "Energy saving by introducing waste hot water recovery system to autoclave in infusion manufacturing process line" ID_AM028

C.4. Emission sources and calculation of emission reductions

<Means of validation>

The proposed project (now commissioned and in operation) aims to reduce emissions from

CNG sources through installation of waste hot water recovery system to an infusion manufacturing process (IMP) line. This reduces the amount of steam supplied by a boiler for heating boiler, which in turn results in lower consumption of CNG in the boiler thus resulting in lower emissions than the reference condition. In the reference condition, the autoclave is used in sterilisation of infusion solutions, wherein one end of the autoclave is connected to the steam source (the boiler) which heats the water from 30 deg C to 121 deg C. This steam is used to sterilise the infusion solutions. However the water after circulation is not recovered and is disposed. Thus for each cycle the water is again heated from 30 deg C resulting in higher emissions due to higher energy consumption from the CNG boiler.

In project condition, high efficiency autoclaves, recovers the steam after circulation thus resulting in lower energy consumption and subsequently lower emissions. In the project scenario, the high efficiency autoclave relies on grid as source of power for its operations.

Reference emissions are calculated with the quantity of steam supplied to the heat exchanger, the ratio of heat quantity required under the project condition and the reference condition, the ratio of temperature difference under the project condition and the reference condition, fuel consumption by the boiler, net calorific value of fuel consumed by the boiler, total quantity of steam generated by the boiler supplying steam to the heat exchanger in the project IMP line, and GHG emission factor of fuel consumed by the boiler.

In the water cycle of the reference system, pure water is produced and drained in each batch process. On the other hand, in the water cycle of the project system, pure water is produced at the first batch process, then recovered and reused for multiple batch processes. Therefore, the electricity consumption for producing pure water is reduced in the project system compared to the reference system. Net emission reductions are ensured by excluding the emission reductions by the reduction of the electricity consumption for producing pure water.

The reference emissions RE is monitored ex post by the following parameters:

Monitoring point 01: NPJ,i,p: Total number of batch process implemented in the project IMP line i during the period p. Units: times/p.

Monitoring point 02: DP,i,p: Total number of hot water drainage from the project IMP line i duting the period p. Units: times/p.

Monitoing point 03:QSP,i,p: Total quantity of steam supplied to the heat exchanger in the project IMP line i during the period p. Units: tonnes/p.

Monitoring point 04: Delta TPJ,i: Temperature difference between the temperature specified in the GMP guideline and the temperature of recovered hot water flowing into the heat exchanger in the project IMP line i. degree celsius.

Monitoring point 05: Delta TRE: Temperature difference between the temperature specified in the the GMP guideline and the temperature of pure water flowing into the heat exchanger in the first batch after drainage. Units degree celsius.

Monitoring point 06: SGPJSpecific Gravity of pure water. Units: kg/L.
Monitoring point 07: SHPJ Specific heat of water under the project condition. Units kJ/(kg.K)
Monitoring point08: WIPJ,i Water quantity per a batch process of autoclave in the project IMP line i. Units: L/time

The reference emissions are determined using the formula in F.2 of the methodology.
The value for REi,p: Reference emissions by installation of waste hot water recovery system in the project IMP line / during the period p ex-ante. Units tCO2e/p.
The ex ante estimation for each year is given below
For 1st year:
Reference Emissions: 6,844.4 tCO2e/p
Project Emissions: 2.1 tCO2e/p
Net emissions: 6,842.4 tCO2e/p
For 2nd year:
Reference Emissions: 7,628.1 tCO2e/p
Project Emissions: 2.3 tCO2e/p
Net Emissions: 7,626.1 tCO2e/p
For 3rd Year to 7th year:
Reference Emissions: 9,332.8 tCO2e/p
Project Emissions: 2.7 tCO2e/p
Net Emissions: 9,330.1 tCO2e/p
The file: JCM_ID034_MPS_draft.xls which provides the monitoring plan was cross checked for consistency with methodology by the assessment team of KBS and found to be correct. However CAR 01 CAR 02 was raised and closed subsequently as per the discussions below

<Findings>
Please state if CARs, CLs, or FARs are raised, and how they are resolved.
CAR 01 was raised with respect to the reference diagram not being clear with respect to energy sources other than the CNG ones. The flow of steam in the process was not adequately expressed. In response the PP submitted the revised flow diagram and elaborated on each of the monitoring point which is used for ex post monitoring of the parameters in the revised PDD.
CAR 02 was raised wherein inconsistencies in use of formula as per methodology was identified.
In the revised PDD, the following points were explained: (note this has to be interpreted with the flow diagram given in section C.2 of the PDD v2.0)
Monitoring point 1: Total number of batch processes implemented in the project IMP line.
Monitoring point 2: Total number of hot water drainage from the project IMP line

Monitoring point 3: Total quantity of steam supplied to the heat exchanger in the project IMP line
Monitoring point 4: Fuel consumption by the boiler
Monitoring point 5: Total quantity of steam generated by the boiler
Monitoring point 6: Electricity consumption by the project recovery pump in the project IMP line
△TRE: Monitoring point for temperature of pure water flowing into the heat exchanger in the first batch after drainage
△TPJ,i: Monitoring point for temperature of recovered hot water flowing into the heat exchanger in the project IMP line
For CAR 02 the PP provieded the pdf file:Explanation on the RE calculation.pdf where the formula was explained stepwise. This effectively clarified the inconistency in using the formula as per the methodology. Accordingly the assessment team at KBS accepted the responses and closed the CAR 02

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

From the discussions in the CAR01, ie., through the revised flow diagram it is clear that there are no backup power sources which are potential emission sources.This was also verified as part of the site visit by the local expert. The process flow is also now clearly stated without ambiguity. Thus CAR 01 point 1 and 2 was suitably addressed by the PP. The use of the formula as per the methodology was clarified through a stepwise explanation of the formula and thus CAR 02 was clsoed.

C.5. Environmental impact assessment

<Means of validation>

The proposed JCM project is to reduce CO2e emission by the reduction of CNG in the boiler using energy efficient autoclave than in the reference condition. The PDD states that an Environmental Impact Assessment (hereinafter referred to as EIA) is not required.

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

CAR 02 (iii) was raised where the PP was asked as a follow up to response of CAR 02 (ii) wherein the groundwater treatment facility required AMDAL while in section D of PDD it was stated otherwise. Since the groundwater facility predates the project activity and is not part of the project boundary, AMDAL for the project activity is not required.

The CAR 2 (iii) was closed successfully as per the discussion below.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

As per the Minister of Environment and Forest ("MOEF") regulation No. P.38/MENLHK/SETJEN/KUM.1/7/2019 AMDAL (Indonesian term for ESIA) has been categorised under 3 categories wherein it is mandatory, The given project activity does not fall under either of the three categories ie., A,B and C and hence is exempt from performing AMDAL Besides the AMDAL was required for groundwater extraction and that activity is not part of the present project activity. The project boundary was checked during the onsite visit by the local expert to see if the groundwater facility is part of the project activity and falls within the project boundary. Local expert confirmed that the groundwater facility is not part of the project boundary. Thus the statement of PP has been accepted.

C.6. Local stakeholder consultation

<Means of validation>

PPs conducted the stakeholder consultation on 03/02/2023 online and was held between 10:00 to 11:15 am (Indonesian Western Standard Time). The list of participants were determined through the consultation with the Indonesian JCM secretariat. The participants included:

(i) Local Stakeholders

1.Indonesia JCM Secretariat / Coordinating Ministry for Economic Affairs of Indonesia

2.Ministry of Industry

3.Ministry of Energy and Mineral Resources

4.PT Jaya Obayashi

5.PT Taikisha Indonesia Engineering

6.PT Widatra Bhakti

7.PT Amerta Indah Otsuka

Project Participants

1.PT Otsuka Indonesia (PTOI)

2.Otsuka Pharmaceutical Factory, Inc. (OPF)

3.(Project collaborator) Commodum, Inc.

4.(Consultant) Ernst & Young ShinNihon LLC

The local stakeholders provided positive comments for the proposed JCM project. There was no negative issue that requires action to be taken by the PPs which raised through the consultation. It is confirmed through the review of the relevant documents and the interview with the PPs during on-site assessment that the stakeholder consultation process was appropriately conducted to collect stakeholder’s opinion. The summary of the comments received in the consultation and due account of all comments taken by the PPs are fully described in the PDD. The date of stakeholder meeting is not consistent with the date in Minute of Meeting of the stakeholder meeting. Also, the stakeholder implementation process is described incompletely. KBS raised CAR 01 (point 3). These were resolved in as per the

discussions under the findings below

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

CAR 01 (iii): The start date of the operations is 01/01/2024. The local stakeholder consultation was conducted on 03/02/2023 which is 11 months earlier.

Resolution: According to the JCM Project Cycle Procedure (*1) clause 34, the draft Project Design Document is prepared after conducting the local stakeholder consultation (LSC), implying that the LSC is generally conducted before the start of the JCM project. It has been agreed upon between the PP and the government of Japan that the official start date of the project is set as 01/01/2024, and that the LSC is conducted before that. The Indonesian JCM secretariat has also been informed of the LSC through PP's invitation to the consultation. The document (screenshot of the email communication) was provided to support the claim:Submission of a proposed JCM project Energy Saving by Introducing High Efficiency Autoclave to Infusion Manufacturing Factory 2.pdf. The mail communication between the secretariat and the PP dated between 09/12/2023 and 26/12/2023 clearly substantiates the claims made by the PP regarding the start date of the project activity and the stakholder meeting. Thus the CAR 01 (iii) was closed.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

The validation team has concluded that the local stakeholder consultation of the proposed JCM project is adequate.

C.7. Monitoring

<Means of validation>

The Monitoring Plan consists of the Monitoring Plan Sheet and Monitoring Structure Sheet, which complies with the Approved Methodology of JCM_ID_AM028_ver01.0. There are 8 monitoring parameters to be monitored ex-post. There are 16 parameters that are to be fixed ex-ante as per methodology out of which 4 parameters are applicable for the project activity. The PP has adopted the Option C ie, based on the actual measurement using measurement equipments (data used: measured values). The ex post parameters are discussed in section C.4 above, Hence the present discussions is limited to only ex ante values. They are as follows:

1. EFelec: CO2 emissions factor for consumed electricity-0.870 tCO2e/MWh-The data is sourced from "Emission Factors of Electricity Interconnection Systems", National Committee on Clean Development Mechanism (Indonesian DNA for CDM), based on data obtained by Directorate General of Electricity, Ministry of Energy and Mineral Resources, Indonesia, unless otherwise instructed by the Joint Committee.

2 EFelec: For Captive electricity-CO2 emissions factor for consumed electricity-0.0 tCO2e/MWh-CDM methodological tool “TOOL 05: Baseline, project and/or leakage emissions from electricity consumption and monitoring of electricity generation, version 03.0”.Default value: 1.3 tCO2e/MWh. The value used for the prsent project activity is 1.3tCO2e/MWh.

4.△TRE: Monitoring point for temperature of pure water flowing into the heat exchanger in the first batch after drainage.ΔTRE is set ex-ante or ex-post by averaging the data monitored for at least 30 days at pure water tank. 90.4 deg C

5.SGPJ: Specific Gravity of pure water: 1.0 kg/L-Theoritical value

6.SHPJ: Theoretical value provided in table 6 of Cabinet Order No. 357 of 1992, Japan. 4.184 kJ/(kg.K)

The values were checked based on the supporting evidences provided and the references provided. The computation was also checked. However CAR 02 (i) was raised regarding the consistency of the formula with methodology. It was suitably closed after the explanatory document was submitted by the PP.

The roles and responsibility of the personnel are described in the Monitoring Structure Sheet in accordance with the requirements of the applied methodology. The monitoring structure consists of:

1.Deputy Plant Director PT. Otsuka Indonesia-In charge of authorizing the monitoring report.

2.Engineering Dept Main Person in Charge PT. Otsuka Indonesia-Engineering Dept Main Person in Charge PT. Otsuka Indonesia

3.Engineering Dept Deputy in Charge PT. Otsuka Indonesia-In charge of monitoring procedure (data collection, checking and storage), including monitoring equipments and calibrations, and training of monitoring personnel.

The monitoring system at place was checked during the assessment as part of local expert visit to the plant and discussions, and it was found that the monitoring system is in place. Further it was observed that competent personnels are working on the same.

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

CAR 2 (ii) was raised and closed subsequently as discussed above.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

The validation team has concluded that Monitoring Plan of the proposed JCM project complies with the requirements of the methodology and/or PDD and Monitoring Guidelines, and the project participants have ability to implement the described Monitoring Plan, including Monitoring Structure Sheet.

C.8. Modalities of Communication

<Means of validation>

The latest version of MoC was submitted to KBS for review at the time of validation, JCM_ID_F_MoC_ver.01.0, in which a person of Otsuka Pharmaceuticals is nominated as the focal point. The MoC was signed by the authorized representatives of all the PPs with the contact details. KBS has assessed the personal identities including specimen signatures and employment status of the authorized signatories directly through the interview with PPs during on-site assessment. Primary authorized signatory of Otsuka Pharmaceutical Factory Inc is Mr. Hiromitsu FUKUHARA as Sr Manager, of Environmental Management Office, Administrative Department, and alternate authorized signatory is Mr. Yodai IKEDA as Staff of Environmental Management Office, Administrative Department. The contact person is Mr Yodai IKEDA as Staff of Environmental Management Office.It is confirmed that all corporate and personal details including specimen signatures and the information in the MoC are valid and accurate as requested in the JCM Guidelines for Validation and Verification

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

No issues were identified to the requirement.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

The validation team has concluded that the MoC complies with all relevant forms and requirements.

C.9. Avoidance of double registration

<Means of validation>

The representative of focal point entity in MoC, Mr. Hiromitsu FUKUHARA, Sr Manager, of Environmental Management Office, Adminstrative Department, Otsuka Pharmaceutical Factory Inc declares in the MoC and Declaration letter on Avoidance of Double Registraiton that the proposed JCM project is not registered under any other international climate mitigation mechanism other than the JCM. It is confirmed through the check of publicly available information of Clean Development Mechanism (CDM), Verified Carbon Standard (VCS), etc. that the proposed JCM project is not registered under other international climate mitigation mechanisms in terms of the name of entities, applied technology, scale, and the location. Thus, it can be concluded that the proposed JCM project will not result in double counting of GHG emission reductions.

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

No issue was raised to the requirement.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

KBS confirms that the proposed JCM project is not registered under the other international climate mitigation mechanisms and hence will not result in double accounting of GHG emission reductions.

C.10. Start of operation

<Means of validation>

The starting date of the proposed JCM project was initially set as 01/01/2024 in the PDD. It is confirmed through the review of relevant documents, on-site assessment and the interview with the PPs that the operation of the proposed JCM project is planned to start on the date. However KBS raised CAR 01, and this issue was resolved in as per the discussions under the findings below

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

Since the LSC is conducted earlier than the start date of the project which was converyed to the JCM secretariat in Indonesia through PP's invitation to the consultation. Thus the CAR 01 was closed. The screenshot of the email communication was shared as evidence.

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

KBS confirms through the relevant documents and during on-site assessment that the starting date of the proposed JCM project operation has been set appropriately as required by the Guideline of the JCM project.

C.11. Other issues

<Means of validation>

PP submitted the filled in JCM Sustainable Development Implementation Plan Form wherein the net negative effect of the project activity towards SD contribution is considered zero under the following heads:

1) EIA
2) Pollution Control
3) Safety and health
4) Natural Enviornment and biodiversity
5) Economy
6) Social Environment and Community Participation
7) Technology.

TPE assessed the claims and raised CAR 2 (ii) with respect to exemption of EIA (AMDAL)

for the project activity. It was closed successfully based on the discussions below.

<Findings>

Please state if CARs, CLs, or FARs are raised, and how they are resolved.

CAR 2 (ii) PP was requested to provide the supporting evidences against all the claims made in SDIP. The PP stated as follows:

Before public comments opened in December 2023, emails between the project developer (PP) and the Joint Crediting Mechanism (JCM) secretariat clarified concerns about groundwater use in the SDIP project (Section B). The emails explained how groundwater is purified for infusions and how the project is expected to greatly reduce overall water usage. These explanations led to a positive review from the JCM secretariat.

Further details emerged due to additional questions from the TPE. These details include:

- The treatment facility has a capacity of approximately 1,987,000 liters per day (KLD).
- Rejected water from the treatment process (RO reject water) is used for cleaning animal testing areas (rabbit hutches) and on-site gardens.
- The facility is subject to AMDAL, the Indonesian environmental impact assessment process. Based on the last response TPE raised a follow up question regarding the need of AMDAL while in section D of the PDD it was stated that AMDAL was no needed. To which PP replied stating that the groundwater facility predates the existing project activity and is not included in the project boundary of the present project activity. This was confirmed through the site visit as well as the documentary evidences submitted by the PP. Besides this is in line with the requirements under para 48.49 under section 6.6 of the JCM Guidelines on Validation and Verification ver 1.0. Thus the finding was closed

<Conclusion based on reporting requirements>

Please state conclusion based on reporting requirements.

The statements under SDIP was accepted based upon the successful completion of the CAR 2 above.

D. Information on public inputs

D.1. Summary of public inputs

In line with the JCM Project Cycle Procedure, the PDD was to be made publicly available for 30 days to invite public comments. The PDD was made publicly available in line with the requirements of the procedure for the period of 25/12/2023 to 23/01/2024 as per https://www.jcm.go.jp/id-jp/information/497

D.2. Summary of how inputs received have been taken into account by the project participants

Based on information through accessing the JCM website till 18/03/2024, no comment was received during the above period to receive public inputs. Thus no action was required to be taken by the PPs to satisfy the JCM requirement.

E. List of interviewees and documents received

E.1. List of interviewees

Mr M Faizal A Pt Otsuka Indonesia Production Department
Mr Kristian Pt Otsuka Indonesia Engineering Department
Mr Shandi Pt Otsula Indonesia Production Department
Mr Yasutaka Emoto Pt Otsuka Indonesia Deputy Plant Director
Mr Yodai Ikeda Pt Otsuka Pharmaceutical Factory Inc., Administrative Department

E.2. List of documents received

1.JCM_ID_F_PDD_ver02.0_Otsuka Pharmaceutical Factory
2.MoC_Otsuka Pharmaceutical Factory
3.Technical Specifications and Drawings
4.Declaration Letter
5.Monitoring Structure
6.Monitoring System Flow
7.Explanation on the RE calculation
8.Submission of a proposed JCM project Energy Saving by Introducing High Efficiency Autoclave to Infusion Manufacturing Factory 2
9.JCM_ID034_MPS_draft_commented
10.Emission Factors of Electricity Interconnection Systems" ("Faktor Emisi Gas Rumah Kaca (GRK) Sistem Interkoneksi Ketenagalistrikan" in Indonesian language) https://gatrik.esdm.go.id/frontend/download_index/?kode_category=emisi_pl
11. List of Parameters for MPS spreadsheet

Annex Certificates or curricula vitae of TPE's validation team members, technical experts and internal technical reviewers

Please attach certificates or curricula vitae of TPE's validation team members, technical experts and internal technical reviewers.

Certificate of Competence

Personnel Name	Mr. Sanjay Kumar Krishnan Kutty				
Schemes	☒ CDM	☒ GCC	☒ GS	☒ VCS	☐Other GHG Schemes (mention here)

Qualified to work as			
Team Leader	☒	Technical Expert	☒
Validator/Verifier	☒	Financial Expert	☐
Technical Reviewer	☒	Local Expert (India)	☒

Area(s) of Technical Expertise	
Sectoral Scope	**Technical Area**
SS 1: Energy industries (renewable/non-renewable sources)	TA 1.2. Renewables
SS 3: Energy demand	TA 3.1. Energy demand
SS 13: Waste handling and disposal	TA 13.1. Solid waste and wastewater
Approved by (Manager Competence)	Dr. Rajesh Monga
Approval date	14-08-2023

History of the document

Version	Date	Nature of revision	Reviewed by QM (Date)	Approved by MD (Date)
1.0	XX Dec 2011	Initial adoption.	XX Dec 2011	XX Dec 2011
1.1	05-01-2023	Revised to include name of the schemes	05-01-2023	06-01-2023

Certificate of Competence

Personnel Name:	Kusheru Wibowo		
Qualified to work as:			
Team Leader	☒	Technical Expert	☒
Validator/Verifier	☐	Financial Expert	☐
Technical Reviewer	☐	Local Expert	☒
Area(s) of Technical Expertise			
Sectoral Scope	**Technical Area**		
SS 1: Energy industries (renewable/non- renewable sources)	TA 1.1. Thermal energy generation		
SS 1: Energy industries (renewable/non- renewable sources)	TA 1.2. Renewables		
SS 5: Chemical industry	TA 5.1. Chemical industry		
SS 12: Solvents use	TA 12.1. Chemical industry		
SS 13: Waste handling and disposal	TA 13.1. Solid waste and wastewater		
Approved by (Manager C & T)	Ritu Arora Sehgal		
Approval date:	13/06/2023		

Certificate of Competence

Personnel Name	S.Ranganathan				
Schemes	☒ CDM	☒ GCC	☒ GS	☒ VCS	☐Other GHG Schemes (mention here)

Qualified to work as			
Team Leader	☒	Technical Expert	☒
Validator/Verifier	☒	Financial Expert	☐
Technical Reviewer	☒	Local Expert (India)	☒

Area(s) of Technical Expertise	
Sectoral Scope	**Technical Area**
SS 01: Energy industries (renewable/non-renewable sources)	TA 1.1: Thermal energy generation from fossil fuels and biomass including thermal electricity from solar
	TA 1.2: Energy generation from renewable energy sources
SS 2: Energy distribution	TA 2.1. Energy distribution
SS 3: Energy demand	TA 3.1. Energy Demand
SS 5: Chemical industry	TA 5.1 Chemical industry
SS 12: Solvents use	TA 12.1 Chemical industry
SS 13: Waste handling and disposal	TA 13.1 Waste Handling and Disposal
	TA 13.2 Manure
Approved by (Manager Competence & Training)	Shikha Sharma
Approval date	05-05-2022

History of the document

Version	Date	Nature of revision	Reviewed by QM (Date)	Approved by MD (Date)
1.0	XX Dec 2011	Initial adoption.	XX Dec 2011	XX Dec 2011
1.1	05-01-2023	Revised to include name of the schemes	05-01-2023	06-01-2023